

PATENT
Docket No. H 3190 PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of
Bernd Fabry

Serial No. 09/554,386

Filed: 07/19/00

TITLE: HYPOCHOLESTEREMIC PREPARATIONS CONTAINING
PHYTOSTENOLESTERS OF CONJUGATED FATTY ACIDS, AND
METHODS OF REDUCING SERUM CHOLESTEROL LEVELS
USING THE SAME

Examiner: S. Qazi, Ph.D.

Art Unit: 1616

CERTIFICATE OF MAILING

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June 5, 2002

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APPEAL BRIEF TRANSMITTAL

Commissioner for Patents
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Sir:

Appellants' appeal brief, in triplicate, is transmitted herewith in accordance with 37 CFR 1.192.

Please charge the required fee of \$320.00 to our Deposit Account No. 50-1177. This paper is enclosed in triplicate. Order No. 02-0308.

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Respectfully submitted,

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BY: Rose A. Stowe DATE: June 5, 2002
Rose A. Stowe

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Patent Application of Bernd Fabry : Group Art Unit: 1616
Appln. No.: 09/554,386 : Examiner: S. Qazi, Ph.D.
Filed: July 19, 2000
For: HYPOCHOLESTEREMIC PREPARATIONS : Attorney Docket
CONTAINING PHYTOSTENOLESTERS OF : No.: H 3190 PCT/US
CONJUGATED FATTY ACIDS, AND
METHODS OF REDUCING SERUM
CHOLESTEROL LEVELS USING THE SAME :

APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Pursuant to the Notice of Appeal filed on December 5, 2001, via facsimile, and received by the U.S. Patent & Trademark Office on the same date, Appellants submit herewith a Brief On Appeal under 37 C.F.R. §1.192, appealing the Examiner's final rejection of pending claims 11-30, as set forth in the final Office Action dated June 5, 2001 (Paper No. 9), as maintained in the Advisory Action dated November 26, 2001 (Paper No. 14). This Brief On Appeal is being timely filed as a Petition for a four-month extension of time, up to and including June 5, 2002, including an authorization to charge fees, is being submitted herewith.

Appellant respectfully requests consideration by the honorable Board of Patent Appeals and Interferences and reversal of the Examiner's rejection of all pending claims based on the arguments set forth in the attached brief.

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REAL PARTY IN INTEREST

The real party in interest in the instant appeal is Cognis Deutschland GmbH & Co. KG, a German company having a place of business at Henkelstraße 67, 40589 Düsseldorf, Germany.

RELATED APPEALS AND INTERFERENCES

Appellant is not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

STATUS OF THE CLAIMS

Claims 11-30 are pending in the instant application on appeal. All of the pending claims are the subject of the instant appeal.

Claims 11-30 stand finally rejected under 35 U.S.C. §103(a), as being unpatentable over European Patent Application No. EP0594612 of Miettinen, *et al.* ("Miettinen"), in view of Alexander Leaf, *et al.*, "Medical Progress: Cardiovascular Effects on n-3 Fatty Acids", THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 318, No. 9, pages 549-557 (March 3, 1988), (referred to as "Alexander, *et al.*" by the Examiner, and hereinafter referred to synonymously as "Leaf" and "the Leaf Article").

All other previous rejections have been withdrawn by the Examiner.

STATUS OF AMENDMENTS

No amendments have been filed in the instant application on appeal subsequent to the Examiner's final rejection of claims 11-30. Appellant's Request for Reconsideration After Final, filed on November 5, 2001 ("the Request for Reconsideration After Final"), has been considered but was not deemed to place the instant application in a condition for allowance, as indicated in Paper No. 14. An appendix containing a copy of the claims involved in the appeal, in accordance with 37 C.F.R. §1.192(c)(9), is attached as Appendix A.

SUMMARY OF THE INVENTION

Appellant surprisingly discovered that phytostenol esters of conjugated fatty acids exhibit significantly better cholesterol-reducing activity than comparable phytostenol esters derived from saturated fatty acids, monounsaturated fatty acids or polyunsaturated fatty acids having two or more unconjugated double bonds. (See, Appellant's Specification, p. 2, lines 22-29). Accordingly, Appellant's claimed invention provides improved compounds for the reduction of cholesterol content in the blood of an animal, (e.g., a human). Appellant's invention is a significant and unexpected improvement over the prior art. Kusman

One embodiment of Appellant's claimed invention is directed to methods of reducing serum cholesterol content in a mammal, comprising: (i) providing a hypocholesteremic preparation comprising at least one phytostenol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms; and (ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal. Another aspect of Appellant's claimed invention is directed to hypocholesteremic preparations comprising at least one phytostenol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms. (See, e.g., Appellant's Specification, the Examples beginning at p. 8, line 31 and the Claims set forth in Appendix A).

As discussed in Appellant's Specification, a known prior art disadvantage associated with the incorporation of phytostenol esters into foodstuffs, where the phytostenol esters are based on saturated fatty acids, monounsaturated fatty acids or polyunsaturated fatty acids having two or more unconjugated double bonds, is that the esters may only be included in small amounts. (See, e.g., Appellant's Specification, p. 2, lines 1-12). Otherwise there is the danger that they will negatively impact the taste and/or the consistency of the foodstuffs. (*Id.*).

As described above, hypocholesteremic preparations, and methods for their use, in accordance with Appellant's claimed invention surprisingly exhibit significantly improved cholesterol reducing activity over phytostenol derivatives derived from non-conjugated fatty acids. It is a significant advantage to use a phytostenol ester having such increased activities when preparing foodstuffs, where increased concentration of additives, such as phytostenol esters,

can negatively affect the taste and/or other aesthetic properties of the foodstuff. (See, e.g., Appellant's Specification, p. 2, lines 1-5).

Specifically, as evidenced by the Examples set forth in Appellants' Specification, hypocholesteremic preparations in accordance with Appellant's claimed invention, reduce serum cholesterol levels, on average, about 10% more than phytosterol esters of non-conjugated acids. After 48 hours, non-conjugated acid esters reduce serum cholesterol levels to an average of 28% in laboratory animal specimens, whereas after the same time period, phytosterol esters of conjugated fatty acids reduce serum cholesterol levels to an average of 18%. (See, Appellant's Specification, pp. 8-9, Table 1).

ISSUES

- (1) Are the combined teachings of Miettinen and the Leaf Article, each of which fails to teach or suggest phytosterol esters of *conjugated* fatty acids, insufficient to render Appellant's claimed invention *prima facie* obvious?
- (2) Even if a *prima facie* case of obviousness could be established based upon the combined teachings of Miettinen and the Leaf Article, does Appellant's showing of unexpected and significantly improved results with respect to the cholesterol-reducing properties of the claimed invention overcome such a *prima facie* case of obviousness?

GROUPING OF THE CLAIMS

All of the pending claims stand or fall together for the purposes of the instant appeal.

ARGUMENT

I. The Examiner's Rejection Under 35 U.S.C. §103(a) is Improper

A. The Rejection of Claims 11-30 Over Miettinen in View of Leaf

In Paper No. 9, the Examiner reiterates her rejection of claims 11-30 under 35 U.S.C. §103(a), as being unpatentable over Miettinen, in view of the Leaf Article, and makes the rejection final.

In Paper No. 9, the Examiner reiterates her contention that Miettinen teaches a "fatty acid composition of β -sitostanol ester mixtures containing large amount of monoenes and polyenes", and that Miettinen teaches an enhanced efficacy of such compositions in lowering serum cholesterol levels, citing lines 40-45 and 56-68 of page 4, and Examples 1-3. (See, Paper No. 9, p. 3 (*emphasis added by Examiner*)). The Examiner again acknowledges that Miettinen fails to teach phytostenol esters of conjugated acids, or the use thereof in reducing serum cholesterol levels. (See, Paper No. 9, p. 3). However, the Examiner again contends that the Leaf Article teaches "n-3 fatty acids for lowering the low-density lipoprotein (LDL) cholesterol", citing the last paragraph of column 2, at page 549. (*Id.*). The Examiner argues that this disclosure somehow alleviates the deficiencies of Miettinen. The Examiner also reiterates all of her previous assertions and contentions concerning the references and their teachings, as set forth in Paper No. 7.

In Paper No. 9, the Examiner responds to Appellant's arguments set forth in the Response filed on March 19, 2001, by acknowledging Appellant's argument that Miettinen does not teach conjugation. The Examiner then notes her disagreement with Appellant's argument "because polyenes and monoenes are conjugated." (Paper No. 9, p. 2).

B. Appellants' Traversal

Appellant respectfully traversed the Examiner's rejection in the Request for Reconsideration After Final, and initially in Appellant's Request for Reconsideration, filed on March 19, 2001, in response to the Office Action mailed December 19, 2000 (Paper No. 7)

Appellant again strenuously, but respectfully, traverses the Examiner's rejection and her contentions and arguments in support thereof, for the reasons set forth below.

C. Requirements for Establishing Prima Facie Obviousness

It is well-settled that in order to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto the Appellant, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the

desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in the Applicant's Specification. (M.P.E.P. §2143).

D. *The Teachings of Miettinen and Leaf Fail to Satisfy the Requirements for Prima Facie Obviousness*

Appellant would first like to point out that neither reference teaches or suggests phytostenol esters of *conjugated* fatty acids. The Examiner has argued that "polyenes and monoenes are conjugated." (Paper No. 9, page 2). On this basis, the Examiner has argued that the reference to "polyenes and monoenes" in Miettinen provides a suggestion of the claimed esters of conjugated fatty acids. Appellant respectfully disagrees.

For the Examiner's convenience, Appellant attached the definitions of (i) "conjugated fatty acid" and (ii) "conjugated double bonds", (as Attachment A) to the Request for Reconsideration After Final. Attachment A was made of record by the Examiner on November 19, 2001. As indicated on page 306 of Attachment A, a conjugated fatty acid is simply a fatty acid containing *conjugated* double bonds. Additionally, as indicated on the same page of Attachment A, *conjugated* double bonds are "two or more double bonds which alternate with single bonds in an unsaturated compound, ...". (See, Attachment A: Richard J. Lewis, Sr. (*Rvsd. By*), Hawley's Condensed Chemical Dictionary, Twelfth Edition, pages 306 & 932 (1993). (4 pages), (*emphasis added*)). Thus, by definition, a monoene cannot be conjugated. There is only one double bond in a *monoene*.

On page 932 of Attachment A, the definition of (iii) a "polyene" is set forth as "any unsaturated aliphatic or alicyclic compound containing more than four carbon atoms in the chain and having at least two double bonds." (See, *id.*, at page 932). There is no mention of conjugation, much less a requirement that there be conjugation. There is no suggestion that the term polyene, by definition, necessarily suggests compounds having at least two double bonds which alternate with single bonds. When referring to conjugated compounds, the term "conjugated" is expressly used by those of ordinary skill in the art. As used in Miettinen, the

phrase "large amounts of monoenes and polyenes" refers to the total content of unsaturated components in a vegetable oil, and includes monounsaturated fatty acids and polyunsaturated fatty acids. (See, Miettinen, page 4, line 41). The phrase has no relation to *conjugated* fatty acid species, which are not simply polyenes, but compounds that contain at least two double bonds which alternate successively with single bonds.

Thus, regardless of the Examiner's broad assertion that Miettinen teaches β -sitostanol fatty acid ester mixtures containing large amounts of monoenes and polyenes, Appellant maintains that Miettinen does not teach or suggest phytostenol esters of a *conjugated* fatty acid having from about 6 to about 24 carbon atoms.

In fact, Miettinen only notes that "the β -sitostanol fatty acid ester mixture *can be selected* so as to contain large amounts of monoenes and polyenes, . . ." (Page 4, lines 40-41, (*emphasis added*)). Miettinen makes no mention of conjugation. Moreover, Miettinen provides no further guidance as to how the mixture "can be selected" so as to contain monoenes and polyenes. Miettinen discloses the use of vegetable oils in general, and specifically mentions rapeseed oil, coconut oil, sunflower oil, soybean oil, olive oil and corn oil. It is respectfully submitted that most common vegetable oils, in general, do not contain any significant amounts of conjugated fatty acids. Again, for the Examiner's convenience, Appellant attached, Daniel Swern, (*Ed.*), Bailey's Industrial Oil and Fat Products, Vol. 1, Fourth Edition, pages 31, 34-36 (1979) (6 pages), as Attachment B to the Request for Reconsideration After Final. Attachment B was made of record by the Examiner on November 19, 2001. As indicated in Table 1.7 on page 31 of Attachment B, the majority of polyunsaturated fatty acids found in vegetable oils (*e.g.*, safflower, sunflower, cottonseed, linseed, perilla, and other drying oils and seed fats) are linoleic and linolenic oils, which are *not* conjugated. A more commonly occurring fatty acid which is conjugated, *i.e.*, eleostearic acid, is prevalent in tung oil but not common vegetable oils such as those listed in Table 1.7.

Miettinen simply does not teach esters of phytostenols and conjugated fatty acids, nor does the reference suggest such esters. Reference to unsaturation does not, by itself, require any conjugation. Moreover, reference to polyunsaturation does not necessarily mean that any conjugation exists.

Secondly, Appellant respectfully submits that the Examiner's arguments pertaining to the Leaf Article are also incorrect, and inaccurate. The Examiner argues that the Leaf Article "alleviates the deficiency of Miettinen *et al.* because it teaches the n-3 fatty acids for lowering the low-density lipoprotein (LDL) cholesterol." (See, Paper No. 9, p. 3). While the Examiner is correct that the Leaf Article teaches lowered levels of LDL cholesterol in the blood of Eskimos whose diets included large amounts of long chain n-3 polyunsaturated fatty acids, which are commonly found in the fish which make up a large portion of the Eskimos' diet, this teaching is not adequate to alleviate any of the deficiencies of the Miettinen reference.

The polyunsaturated n-3 and n-6 fatty acids disclosed in the Leaf Article are not conjugated. The beneficial n-3 fatty acids disclosed in the Leaf Article are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). (See, Leaf, page 549, col. 1, lines 17-20). The structural formulas for both EPA and DHA are set forth in Figure 1, on page 550 of the Leaf Article. The existence of two single carbon-carbon bonds between each unsaturation in the formulas presented in Figure 1 specifically indicates that there is no conjugation in either EPA or DHA. Furthermore, as specified at page 36 of Attachment B, the structures of EPA and DHA found in marine oils have been confirmed as 5,8,11,14,17-eicosapentaenoic acid and 4,7,10,13,16,19-docosahexaenoic acid. (See, Daniel Swern, (Ed.), Bailey's Industrial Oil and Fat Products, Vol. 1, Fourth Edition, pages 31, 34-36 (1979) ("Attachment B")). As clearly indicated by the structural nomenclature, none of the double bonds are conjugated.

The Leaf Article is directed to the effects of n-3 and n-6 polyunsaturated fatty acids. The designations, "n-3" and "n-6", simply refer to the number of carbon atoms from the methyl-terminus of the fatty acid at which the first unsaturation is located. Again, none of the fatty acids identified in the Leaf Article is conjugated. As previously pointed out in Appellant's response filed on March 19, 2001, the linoleic acid shown in Figure 1 of the Leaf Article is 9,12 linoleic acid. The α -linolenic acid is 9,12,15-linolenic acid. Conjugation of said acids would require double bond locations at 9,11 and 9,11,13 respectively. The Leaf Article focuses on the differentiation in the body between n-3 and n-6 polyunsaturated fatty acids. There is no teaching or suggestion in the Leaf Article to ingest conjugated fatty acids, nor any teaching or suggestion that such ingestion could be undertaken to reduce serum cholesterol levels.

The Examiner appears to address the lack of any express teaching with respect to conjugated fatty acids by noting that the Leaf Article also mentions "dietary fish and fish oil supplements". (*Id.*). Again, while the Leaf Article clearly references fish which contain the taught n-3 fatty acids, the reference makes no mention of any conjugation, and as indicated above, Attachment B notes the structure of such acids derived from marine oils as being non-conjugated.

Moreover, as the Leaf Article specifically teaches the benefit of n-3 polyunsaturated fatty acids, all of which are not conjugated, it would appear that Leaf actually teaches away from hypocholesteremic preparations containing conjugated fatty acids, and instead focuses on the value of the more common, or more regular, "9,12" and "9,12,15" polyunsaturated fatty acids.

Thus, Appellant again submits that neither reference, nor a combination thereof, teaches or suggests each and every element of the claimed invention. Specifically, neither reference teaches the use of conjugated fatty acids in lowering serum cholesterol levels. Moreover, neither reference teaches the use of an ester of a phytostenol compound with a conjugated fatty acid for such a purpose.

Next, Appellant submits that neither Miettinen, nor the Leaf Article, either alone or in combination, contains any teaching or suggestion which would motivate one of ordinary skill in the art to combine and modify their teachings, as suggested by the Examiner, in order to arrive at the claimed invention. As discussed above, neither reference teaches the use of conjugated fatty acids. Absent any specific teaching to use esters of conjugated fatty acids, it cannot reasonably be said that one of ordinary skill in the art would be motivated to modify the references to include the use of such esters. Moreover, based upon Leaf's apparent emphasis on non-conjugated acids, it could be said that the reference teaches away from the suggested modification.

Finally, given the lack of any teaching or suggestion of conjugated fatty acid esters of phytostenol compounds, and given the lack of any teaching or suggestion motivating such a modification of the prior art, one of ordinary skill in the art would not have a reasonable expectation of success, based upon the cited art.

Accordingly, Appellant submits that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Appellant respectfully requests that the Honorable Board reverse the Examiner and withdraw the rejection based upon Miettinen and the Leaf Article.

II. Indicia of Non-Obviousness

A. Appellant's Showing of Significantly Improved Results

Even if it were assumed, for argument's sake, that a *prima facie* case of obviousness could be established based upon any of the cited references, or a combination thereof, and that such a *prima facie* case of obviousness had been established, which it cannot and has not, any such alleged *prima facie* case of obviousness would be overcome by Appellant's showing of unexpected, significant improvements.

As evidenced by the Examples set forth in Appellant's Specification, beginning at page 8, line 31, the phytosterol esters of conjugated fatty acids in accordance with certain embodiments of Appellant's invention exhibit significantly improved cholesterol reducing properties, compared to esters of unconjugated acids. As can be seen from Table 1, esters of conjugated fatty acids performed significantly better than polyunsaturated acid esters with no conjugation (such as those of linoleic acid).

From Table 1, it can be seen that the average relative percentage of radiation labeled cholesterol present in the serum of animal subjects 48 hours after ingestion of the radiation labeled cholesterol and no conjugated acid esters is approximately 28% (arithmetic mean of Comparative Examples C1 and C2). The average relative percentage of radiation labeled cholesterol present in the serum of animal subjects 48 hours after ingestion of the radiation labeled cholesterol in conjunction with phytosterol esters of conjugated acids is approximately 18% (arithmetic mean of Examples 1-5).

This significant improvement is surprising as noted in the Specification. Appellant's Specification specifically states:

Surprisingly, it has been found that phytosterol esters based on conjugated fatty acids exhibit, with respect to reducing the cholesterol content in the blood, considerably higher activity than comparable phytosterol esters derived from saturated fatty acids, monounsaturated fatty acids or polyunsaturated fatty acids having two or more unconjugated double bonds.
(See, Appellant's Specification, page 2, lines 22-29).

It is submitted that Appellant's showing of unexpected and improved results sufficiently rebuts any alleged *prima facie* case of obviousness. Accordingly, Appellant respectfully requests that the Honorable Board withdrawal of all rejections under 35 U.S.C. §103(a) is respectfully requested.

B. Examiner's Rebuttal in Paper No. 14

In Paper No. 14, the Examiner provides her rebuttal arguments in response to the indicia of non-obviousness set forth by Appellant in the Request for Reconsideration After Final. In Paper No. 14, the Examiner argues, "[i]nstantly claimed conjugated double bonds containing stanol/or stenol esters are not compared with prior art unsaturated esters. Results in table 1 of the specification was not found persuasive, because the comparison is not a side by side comparison, see MPEP 716.02(e)." (See, Paper No. 14, ¶¶ 6 & 11).

This is the extent to which Appellant's arguments regarding unexpected, significant improvement have been addressed by the Examiner. Appellant presented his showing in both the Request for Reconsideration filed on March 19, 2001, and in the Request for Reconsideration After Final.

C. Law Pertaining to Indicia of Non-Obviousness

To begin with, the Federal Circuit has held that "the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results." (*In re Soni*, 34 USPQ.2d 1684, 1687 (Fed. Cir. 1995), citing *In re Margolis*, 228 USPQ 940 (Fed. Cir. 1986)). The Federal Circuit also held that, "when an applicant demonstrates *substantially* improved results, . . ., and states that the results were *unexpected*, this should suffice to establish unexpected results *in the absence of* evidence to the contrary." (*Soni*, at 1688 (*emphasis in original*)).

Secondly, with respect to the type of showing necessary, Appellant respectfully submits, that Section 716 of the M.P.E.P. does not require the submission of a "side-by-side" comparison in order to successfully establish unexpected results. Appellant respectfully submits, that section 716.02(e) simply outlines one requirement of a Declaration under 37 C.F.R. §1.132, namely that such a declaration compare the claimed subject matter with the closest prior art available. There is no requirement for a Declaration.

However, section 716.02(b), which is more specifically related to the burden of proof concerning allegations of unexpected results, clearly indicates that both direct and *indirect* comparisons with the prior art may be made.

D. Sufficiency of Appellant's Showing

Regardless of the correctness of the Examiner's contention that §716.02(e) of the M.P.E.P. requires a side-by-side comparison, and contrary to the Examiner's assertion that Appellant failed to set forth a side-by-side comparison, Appellant respectfully submits that the comparative data set forth in the Specification is a sufficient comparison of the invention and the closest prior art available.

Specifically, Appellant compares phytostenol esters of conjugated fatty acids (Examples 1-5) with phytostenol esters of (i) saturated fatty acids (*i.e.*, lauric acid, Comparative Example 1), (ii) monounsaturated fatty acids (*i.e.*, oleic acid, Comparative Example 2), and (iii) *unconjugated* polyunsaturated fatty acids (*i.e.*, linoleic acid, Comparative Example 3).

Thus, Appellant specifically submits that the comparative data most certainly compares the claimed phytostenol esters with "the prior art unsaturated esters." Furthermore, the comparative data need not be present in the form of a Declaration. Data set forth in the Specification must be considered. Finally, the significant improvement shown in the Examples is identified in the Specification as being unexpected.

Accordingly, it is submitted that Appellant's showing of unexpected and improved results sufficiently rebuts any alleged *prima facie* case of obviousness. Appellant submits that significantly improved results shown by direct comparison, as set forth in the Specification, along with Appellant's statement that such improved results are unexpected,

satisfy the required burden under Section 716.02(b) of the M.P.E.P. and *Soni*, absent evidence to the contrary.

CONCLUSION

In view of the arguments set forth above, Appellant submits that the Examiner's rejection under 35 U.S.C. §103(a) is improper, that the Examiner has failed to establish a *prima facie* case of obviousness, that any alleged *prima facie* case of obviousness is sufficiently rebutted by Appellant's showing of significantly improved results, and that all claims on appeal patentably distinguish over the prior art of record and known to Appellant, either alone or in combination. Accordingly, Appellant respectfully requests that the Board find for Appellant and reverse the Examiner's final rejection.

Respectfully submitted,

BERND FABRY

June 5, 2002
(Date)

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APPENDIX A**Claims On Appeal:**

1. CANCELED
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11. A method of reducing serum cholesterol content in a mammal, said method comprising:
 - (i) providing a hypocholesteremic preparation comprising at least one phytostenol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms; and
 - (ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal.
12. The method according to claim 11, wherein the at least one phytostenol ester comprises an ester of β -sitostenol or β -sitostanol.
13. The method according to claim 11, wherein the conjugated fatty acid is selected from the group consisting of conjugated linoleic acid and conjugated fish fatty acids.

14. The method according to claim 11, wherein the conjugated fatty acid comprises conjugated linoleic acid.
15. The method according to claim 11, wherein the at least one phytostenol ester comprises an ester of conjugated linoleic acid and β -sitostenol or β -sitostanol.
16. The method according to claim 11, wherein the hypocholesteremic preparation further comprises a potentiating agent selected from the group consisting of tocopherols, chitosans, phytostenol sulfates, (deoxy)ribonucleic acids, and combinations thereof.
17. The method according to claim 11, wherein the hypocholesteremic preparation further comprises a tocopherol.
18. The method according to claim 11, wherein the hypocholesteremic preparation further comprises a chitosan selected from low-molecular weight chitosans and high-molecular weight chitosans.
19. The method according to claim 11, wherein the hypocholesteremic preparation is encapsulated in gelatin, whereby a gelatin capsule is provided, prior to administering the preparation to the mammal.
20. The method according to claim 18, wherein the at least one phytostenol ester is present in an amount of from about 0.1 to about 50% by weight, based on the total weight of the gelatin capsule.

21. A hypocholesteremic preparation comprising at least one phytostenol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms.
22. The hypocholesteremic preparation according to claim 21, wherein the at least one phytostenol ester comprises an ester of β -sitostenol or β -sitostanol.
23. The hypocholesteremic preparation according to claim 21, wherein the conjugated fatty acid is selected from the group consisting of conjugated linoleic acid and conjugated fish fatty acids.
24. The hypocholesteremic preparation according to claim 21, wherein the conjugated fatty acid comprises conjugated linoleic acid.
25. The hypocholesteremic preparation according to claim 21, wherein the at least one phytostenol ester comprises an ester of conjugated linoleic acid and β -sitostenol or β -sitostanol.
26. The hypocholesteremic preparation according to claim 21, wherein the hypocholesteremic preparation further comprises a potentiating agent selected from the group consisting of tocopherols, chitosans, phytostenol sulfates, (deoxy)ribonucleic acids, and combinations thereof.
27. The hypocholesteremic preparation according to claim 21, wherein the hypocholesteremic preparation further comprises a tocopherol.
28. The hypocholesteremic preparation according to claim 21, wherein the hypocholesteremic preparation further comprises a chitosan selected from low-molecular weight chitosans and high-molecular weight chitosans.

29. The hypocholesteremic preparation according to claim 21, wherein the hypocholesteremic preparation is encapsulated in gelatin, whereby a gelatin capsule is provided.

30. The method according to claim 28, wherein the at least one phytostenol ester is present in an amount of from about 0.1 to about 50% by weight, based on the total weight of the gelatin capsule.

09/554,386

DOCKET NO. H 3190 PCT/US (COGNIS)
 SERIAL NO. ~~09/554,386~~ ATTORNEY ARE/RAS
 APPLICANT Rath, et al.

The patent office acknowledges, and has stamped hereon the date of the receipt of the items checked below:

- ☐ AFFIDAVIT OR DECLARATION
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☐ APPEAL NOTICE
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☐ BASE ISSUE FEE
☒ BRIEF - IN TRIPLICATE
☒ CERT. OF MAILING BY EXPRESS MAIL & TRADEMARK OFFICE
 6-5-02 (DATE)
☒ EXTENSION OF TIME REQUEST (4 MOS.)
☒ LETTER
☒ LETTER - CHARGE DEPOSIT ACCOUNT (2) (IN TRIP)
☐ LICENSE PETITION (35 USC 184)
☐ DRAWINGS
☐ PCT TRANSMITTAL LETTER PTO-1390
☐ PETITION
☐ PRIORITY CLAIM
☐ REFERENCES/IDC
☐ RESPONSE
☐ TERMINAL DISCLAIMER
☐ PCT TRANSMITTAL LETTER PTO-1382 (IF DUPLICATE)
☐ PCT REQUEST PAGES; DESCRIPTION PAGES;
☐ CLAIMS PAGES; ABSTRACT PAGES
☐ FEE CALCULATION SHEET (IN TRIPLICATE)
☐ RESPONSE TO INVITATION TO CORRECT DEFECTS
☐ POWER OF ATTORNEY
☒ OTHER
APPEAL BRIEF TRANSMITTAL FORM



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